Remarks

Claims 20, 21, 24, 28-30, 32-39, 47-49, and 51-55 are currently pending in the captioned application, including independent claims 20, 30, and 48 and withdrawn claims 30, 32-39, and 47.

In the Office Action, independent claims 20 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tasiaux, et al. (International Publication No. WO 01/21228) in view of Nguyen-Thien-Nhon (U.S. Patent No. 6,001,126).

Tasiaux, et al. discloses cardiac valves made from a biological or biocompatible tissue having a resistance to calcification. Specifically, an appropriate biological tissue may be a tissue removed from the heart of an animal, from the aortic valve of an animal, or from the pericardium of an animal (p. 2, ll. 25-28). These tissues, however, are not high elastin content tissues as are found in the pending claims. For instance, and as described in the captioned application (see, e.g., paragraphs [0050], [0053], and Figure 4), pericardial tissue contains only about 2% by weight elastin, and aortic cusps contain less than 10% elastin. In contrast, the fixed implantable tissue of the pending claims include an elastin content of at least about 30% by weight. Thus, Tasiaux, et al. fails to disclose limitations of pending independent claims 20 and 48, and specifically, Tasiaux, et al. fails to disclose an implantable fixed tissue including an elastin content of at least about 30% by weight of the implantable fixed tissue.

As such, Tasiaux, et al. was combined with Nguyen-Thien-Nhon in an attempt to render the claims obvious. However, Nguyen-Thien-Nhon also fails to disclose or suggest an implantable fixed tissue including an elastin content of at least about 30% by weight of the implantable fixed tissue.

The implantable fixed tissue of Nguyen-Thien-Nhon is a stentless heart valve. This implantable fixed tissue is formed of a preserved segment of mammalian aorta that includes an inflow rim or inflow end IE, an outflow rim or outflow end OE, the aortic valve leaflets therewithin, and segments of the right and left main coronary arteries extending from the aortic segment (col. 4, ll. 18-27). At least portions of this implantable fixed tissue, for instance the aortic valve leaflets within the aortic segment, are extremely low in elastin content. Accordingly, the implantable fixed tissue *as a*

whole cannot be assumed to have a high elastin content as is found in the implantable fixed tissues of the pending claims.

A reference must be read *as a whole*. According to Nguyen-Thien-Nhon, the implantable fixed tissue is the entire preserved segment as described. Thus, even if the references were combined as suggested in the Office Action, the resulting fixed tissue would include the segment of Nguyen-Thien-Nhon, which includes all of an inflow rim or inflow end IE, an outflow rim or outflow end OE, the aortic valve leaflets therewithin, and segments of the right and left main coronary arteries extending from the aortic segment, and this segment could be treated according to the teachings of Tasiaux, et al. This treated segment, i.e., this implantable fixed tissue, includes the inflow rim, an outflow rim, the aortic valve leaflets, and segments of the right and left main coronary arteries. This fixed tissue includes at least certain portions with extremely low elastin content. No showing has been made to suggest that this segment includes an elastin content of at least about 30% by weight of the implantable fixed tissue, as is found in independent claims 20 and 48.

Applicants respectfully maintain that independent claims 20 and 48 patentably define over the cited references for at least the reason that even if combined as suggested, the combined references still fail to teach limitations of the claims. Neither Tasiaux, et al. nor Nguyen-Thien-Nhon disclose or suggest an implantable fixed tissue including an elastin content of at least about 30% by weight of the implantable fixed tissue. Accordingly, Applicants respectfully maintain that independent claims 20 and 48 patentably define over the cited references and request withdrawal of the rejection.

In the Office Action, independent claims 20 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tasiaux, et al. in view of Nguyen-Thien-Nhon and further in view of Yang (U.S. Patent Application Publication 2003/0078659).

Yang is directed to methods for forming elongated graft elements, and specifically, prostheses for reconstruction or repair of ligaments, tendons, or other body wall deficiencies (p. 1, ¶[0009]). The tubular tissue of the graft elements is processed to form an elongated graft element that has a different orientation from the original orientation of the tubular tissue, so that the tissue can have sufficient strength and

initial tension to be used as a graft for ligaments, tendons, and body wall deficiencies (p. 2, ¶[0023]). Luminal or tubular tissues including venous tissue such as vena cava can be utilized (p. 2, ¶[0025]).

Applicants respectfully submit that proper rationale for the suggest combination does not exist. Tasiaux, et al. and Nguyen-Thien-Nhon, et al. are both directed to the formation of bioprosthetic heart valves. Heart valves maintain the unidirectional flow of blood in the heart. Specifically, the valve leaflets open and close depending on the difference in pressure on each side and allow unidirectional blood flow through the valve. In contrast, the graft elements of Yang are for use as ligaments, tendons, or body wall defects. These materials require sufficient strength and initial tension for the desired use. The strength of a starting tubular tissue when stretched in the longitudinal orientation is not sufficient for use as a ligament or tendon graft element (p. 2-3, ¶[0031]). Accordingly, to form the implants, a starting tubular tissue is split and then folded, wrapped, or rolled such that the longitudinal axis is essentially the transverse circumferential orientation of the pre-split tissue. The folded, wrapped or rolled tissue is then secured (p. 3, ¶[0034]-[0035]). The multi-layer graft element including the alteration in tissue orientation now provides greater strength and better initial tension (p. 3, ¶[0036]) so as to be utilized as an implant for a tendon, ligament or body wall defect repair or reconstruction.

Applicants respectfully submit that the proposed modification of Tasiaux, et al. would render the invention of Tasiaux, et al. unsatisfactory for its intended purpose, and as such, there is no suggestion or motivation to make the proposed modification. Tasiaux, et al. is directed to the formation of a cardiac valve. A cardiac valve includes tissue leaflets that open and close under a differential pressure and defines an inner lumen therethrough to allow unidirectional blood flow through the valve. The implant material of Yang, on the other hand, is a graft element that includes at least two layers of a tissue, and thus is much thicker than tissue utilized in forming a cardiac valve.

Applicants respectfully submit that the proposed modification, in which the multilayer graft element of Yang, et al. is incorporated into a cardiac valve according to the methods of Tasiaux, et al. and Nguyen-Thien-Nhon, et al. would produce an

implant unsuitable for use as a cardiac valve. Specifically, the resulting multilayer graft element would be too thick to form workable valve leaflets and would be too thick to allow unidirectional blood flow through the formed valve.

Accordingly, Applicants respectfully submit that independent claims 20 and 48 patentably define over Tasiaux, et al. in view of Nguyen-Thien-Nhon and further in view of Yang, and request withdrawal of the rejection.

Applicants also respectfully submit that for at least the reasons indicated above relating to corresponding independent claims 20 and 48, the pending dependent claims patentably define over the references cited. However, Applicants also note that the patentability of the dependent claims certainly does not hinge on the patentability of independent claims. In particular, it is believed that some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims.

As a final matter, Applicants respectfully request rejoinder of withdrawn claims 30, 32-39 and 47 to the pending application. The claims are related as subcombination/combination claims. Such claims require two-way distinctness for maintenance of a restriction requirement. Specifically, the inventions are distinct if it can be shown that a combination as claimed (A) does not require the particulars of the subcombination as claimed for patentability and (B) the subcombination can be shown to have utility either by itself or in another materially different combination (MPEP §806.05(c)). In the present instance, Applicants submit that the combination as claimed in independent claim 30 requires the implantable fixed tissue as claimed in the subcombination of independent claim 20. Accordingly, the two-way distinctness requirement has not been met, and Applicants request rejoinder of the claims.

It is believed that the present application is in complete condition for allowance and favorable action is therefore requested. Examiner Khan is invited and encouraged to telephone the undersigned at her convenience should there be any questions with regard to this application.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

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